(1)

No. 83-1925

IN THE

Supreme Court of the United States

OCTOBER TERM 1984

HILLSBOROUGH COUNTY, FLORIDA AND
HILLSBOROUGH COUNTY HEALTH DEPARTMENT

V.

AUTOMATED MEDICAL LABORATORIES, INC.

**ON APPEAL FROM
THE UNITED STATES DISTRICT COURT
FOR THE ELEVENTH CIRCUIT**

JOINT APPENDIX

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JURISDICTIONAL STATEMENT FILED MAY 22, 1984
PROBABLE JURISDICTION NOTED JANUARY 14, 1985

63 pp

INDEX

Record Page

DOCKET 1

COMPLAINT WITH EXHIBITS 5

Exhibit A - Hillsborough County Ordinance #80-11 21

Exhibit B - Hillsborough County Ordinance #80-12 24

Exhibit C - Rules and Regulations Pursuant to Hillsborough County Ordinance #80-12 32

ANSWER 40

OPINION OF UNITED STATES DISTRICT COURT FOR THE MIDDLE DISTRICT OF FLORIDA 40

JUDGMENT OF THE DISTRICT COURT 47

OPINION OF THE UNITED STATES COURT OF APPEALS FOR THE ELEVENTH CIRCUIT 48

JUDGMENT OF THE CIRCUIT COURT 60

UNITED STATES DISTRICT COURT
MIDDLE DISTRICT OF FLORIDA
TAMPA DIVISION

CLOSED NOV. 1, 1982

Plaintiffs
AUTOMATED MEDICAL LABORATORIES INC

Defendants
HILLSBOROUGH COUNTY, FLORIDA and
HILLSBOROUGH COUNTY HEALTH DEPARTMENT

Cause
(Cite the U.S. Civil Statute under which the case is filed and write a brief statement of cause)
28 USC S1343 (3) and 42 USC S1983, to enjoin the enforcement of two Hillsborough Co ordinances & the regulations issued thereunder on grounds that they are unconstitutional under the commerce & supremacy clauses of the fifth and fourteenth amendments

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Date		NR	Proceedings
1981			
Dec	21	1	Complaint Filed (summ issued)
Jan	12	2	S&C ret ex 1-7-82 re: President Chairman or chief Exec. of Hillsborough Cty,
	12	3	S&C ret ex 1-7-82 re: Dr. Donald Kwalick Director Hillsborough co Health Dept
	27	4	Deft M/to dismiss;memo of law in supp
Feb	12	5	S&C ret ex 1-29-82 re: E J Salcines State Atty in Hillsborough Co
Jan	29*	6	Deft notice of appearance of counsel
Feb	4	7	Pltfs memo of law in supp of pltfs M/for a preliminary injunction

	4	8	Pltfs M/for preliminary injunction
	10	9	Notice of hearing on M/for preliminary injunction Feb 17, 1982 at 2:00 pm rm 435 before WC (m)
	12	10	ORDERED: hearing previously set for Feb 17, 1982 is cont, pltf shall file a response to defts M/to dismiss by Mar 1, 1982, defts shall file a response to pltfs M/for preliminary injunction by Mar 7, 1982, trial of this action on the merits will be consolidated with the hearing on the applic for preliminary injunction pursuant to FRCP rule 65(a)(2) & will be advanced on the cts calendar (m)
Mar	2	11	Pltf's MEMO in opposition to defts' M/Dismiss
	4	12	Ctf. of Service of pltf's 1st interrogs. & req. for production to defts.
	4	13	MOTION to shorten time for defts. to resp to pltf's 1st interrogs. & req. for production, fld. by pltf.
	8	14	Defs' Memo. of Law in Opp. to Pltf's M/for a Preliminary Injunct.
	8	15	ORDERED: Defs' M/to Dismiss is denied; Pltf's M/to Shorten Time to Resp. to Interrogs is denied. (m)
	8	16	ORDERED: Disc. cutoff 5/7/82; P/T conf. 5/21/82; N/J Trial during wks. of June 7, 14 and 21, 1982. (m)
	18	17	ANSWER: fld by defts.
Apr	2	18	Pltf's 1st. Interrogs. and Reqs. for Prod. of Docs.
	7	19	Cert. of Service of Interrogs. and Req. for Prod. of Docs.
	8	20	Not/taking depos. April 29, 1982: David Carr, at 10:00 AM, in St. Petersburg Haven Poe, at 11:30 AM in St. Petersburg Dr. H. A. Moore, at 2:00 PM in St. Petersburg
May	3	21	Defs' M/for Ext. of Time for Disc.
	6	22	Depo of Haven Poe (4/29/82)
	6	23	Depo of David Carr (4/29/82)
	6	24	ORDERED: The M/for Ext. of Time for Disc. is granted; Disc. is ext. until 5/17/82. (m)
	7	25	Def's M/for Appt. of Process Server.
	7	26	Not. of Taking Depos of Mili Lamas and Dennis Healey (5/13/82)
	7	27	Depo of Helen A. Moore (4/29/82)
	7	28	M/for Appt. of Process Server-GRANTED (TGW)
	10	29	Pltf's Objects. to Def. Hills. Co.'s 1st Interrogs. and Reqs. for Prod. of Docs.
	12	30	Not. of Re-setting P/T Conf. (5/20/82 at 3 PM)
	12	31	Def. Hills. Co.'s M/to Compel.

	12	32	Memo. in Supp. of M/to Compel.
	17	33	Deft's First Interrogs. & Requests for production of documents & Pltf's Objections an responses
	20		PROCEEDINGS: Pretrial conference in open court Case not to be tried before 6/14/82; briefs, FOF & COL due 6/2/82; ELT 1½ days R-82
	21	34	Pltf's Statement Regarding Proposed P/T Stip.
	21	35	Depo of Helen A. Moore, M.D. (4/29/82)
	21	36	Depo of David Carr (4/29/82)
	21	37	Depo of Haven Poe (4/29/82)
	*19	38	P/T Stip. filed.
	24	39	P/T Order filed.
	26	40	Pltf's Suppl. Resp. to Def's 1st Interrogs. and Reqs. for Prod. of Docs.
1982			
Jun	2	41	Pltf's Trial Memo.
	2	42	Pltf's P/T Proposed Findings of Fact and Conclusions of Law.
	2	43	Def's Trial Brief.
	25	44	NOTICE, re-setting NJ Trial for term beg. 7-6-82 before WJC ctc
	28	45	NOTICE filed by Def.
	29	46	MOTION to Reschedule trial by deft. Hillsb. Co.
July	2	47	MEMO in support of M/reschedule, fld.
	2	48	ORDERED: M/to Resched. is granted; This cause is reset for Status Conf. 7/29/82 at 10 AM; Trial is resched. for 9/6/82. (m)
Sep	16		Non-jury trial: Pltf's opening statement; deft defer opening; Pltf's witnesses: Milli Lamas; Dennis Healey; David Michael Carr; Helen A. Moore; Haven Poe; Milli Lamas (recall); Pltf's ex. #'sl-9,11-22 rec'd in evidence; Pltf rests; Deft County' opening statement; Deft Health Dept endorses opening of Deft County; Deft's witness Donald S. Kwalick; Janice K. Platt; Joseph Kotvas; Jerry Bowmer; Fred Arthur Anderson; Paul J. Schmidt; Frank C. Coleman; Herbert W. Smith R-83
	17		PROCEEDINGS: non-jury trial resumed; Deft's witness: Edward Atkins; Closing args of counsel; Matter taken under advisement R-83
Nov	1	49	OPINION filed. R/83
	1	50	FINAL JUDGMENT: Sec. 7 of Hills. Co. Ord. 80-12 and Sec. 4 of the Rules and Regs. Pursuant to Hills. Co. Ord. 80-12 are invalid in that they impose an impermissible burden on interstate commerce, and the Defs. and their agents and

		employees are hereby enjoined from enforcing or attempting to enforce them; As to the other claims of Pltf. Automated Med. Labs., Inc., Judg. is entered in favor of the Defs Hills. Co., Fla. and Hills. Co. Health Dept., and Pltf. shall take nothing. R/83
24	51	NOTICE OF APPEAL from final judgment entered 11/1/82 by pltf; CC of docket entries notice of appeal and appeal transmittal letter forwarded to 11th Circuit; copies of all the above forwarded to all counsel of record along with appeal info sheet sent to counsel for appellant.
1983		
Jan 3	52	TRANSCRIPT of trial proceedings beginning 9/16/82, Vol. I.
3	53	TRANSCRIPT of trial proceedings, vol. II.
3	54	TRANSCRIPT of trial proceedings, vol. III.
14		ENTIRE RECORD SENT TO USCA, ATLANTA, GA.
*		
Nov30'82	55	Deft Hillsborough County's NOTICE OF CROSS APPEAL
Jan31'83	—	Supplement Record sent to USCA, Atlanta
03/12/84	56	TRANSMITTAL LETTER dated 3/8/84 from USCA indicating that Cert. copy of USCA Judgment, Court's opinion, 2 vol. of original record on appeal and 1 box of original exhibits were being returned. Acknowledged by gg.
03/12/84	57	JUDGMENT (USCA): It is now here ordered and holding by this Court that the Judgment of the District Court finding Section 7 of Ordinance 80-12 and §4 of the rules and regulations invalid is AFFIRMED; the Judgment finding the remaining sections of County Ordinances 80-11 and 80-12 and implementing rules and regulations valid is REVERSED; It is further ordered that defendants-appellees pay to plaintiff-appellant the costs on appeal to be taxed by the Clerk of this Court. ISSUED AS MANDATE 3/8/84. Judgment entered by USCA 1/16/84. Microfilm roll #86; document #2102
03/12/84	58	OPINION of USCA: Affirmed in part, reversed in part. (per Judgment #57 above); Microfilm roll #86; document #2103.

UNITED STATES DISTRICT COURT
MIDDLE DISTRICT OF FLORIDA

CASE NO. 81-1161-CIV-WC

COMPLAINT
(INJUNCTIVE RELIEF SOUGHT)

AUTOMATED MEDICAL LABORATORIES, INC.,
Plaintiff,

-vs-

HILLSBOROUGH COUNTY, FLORIDA and
HILLSBOROUGH COUNTY HEALTH DEPARTMENT,
Defendants.

The plaintiff, by way of complaint against the defendants, states:

STATEMENT OF CLAIM

1. This is a civil action by Automated Medical Laboratories, Inc. ("Automated") against Hillsborough County, Florida ("County"), and the Hillsborough County Health Department ("County Health Department") seeking a declaratory judgment and injunctive relief.

THE PARTIES, JURISDICTION AND VENUE

2. Automated is a corporation duly organized and existing pursuant to the laws of Florida, and having its principal place of business in the City of Miami, State of Florida.

3. The County is a political subdivision of the State of Florida existing pursuant to the Florida Constitution, art. 8, §1, and governed by the Board of County Commissioners of Hillsborough County, Florida (the "Commissioners"), pursuant to the Florida Constitution art. 8, §1(e) and Fla. Stat. §§125.001 *et seq.*

4. The County Health Department is an agency of the County existing pursuant to Fla. Stat. §154.01.

5. This Court has subject matter jurisdiction of this action pursuant to 28 U.S.C. §1331 (federal question), 28 U.S.C. §1343 (civil rights), 42 U.S.C. §1983 (civil rights), 28 U.S.C. §2201 (declaratory judgment), and the principles of pendent and ancillary jurisdiction.

6. The acts, omissions and transactions herein complained of occurred in substantial part within the Middle District of Florida; venue lies in the Middle District of Florida pursuant to 28 U.S.C. §1391.

FACTUAL BACKGROUND

7. Automated maintains and operates, and has maintained and operated at all times relevant hereto, through its wholly owned subsidiary, Tampa Plasma Corporation, a plasmapheresis facility located at 1502 West Kennedy Boulevard, Tampa, Florida 33606.

8. Plasmapheresis is a procedure whereby, during a single process, blood is removed from a donor, the plasma is removed from the whole blood, and the red blood cells are returned to the donor.

9. Automated collects plasma from human donors who are reimbursed for their time and effort expended during the donation procedure.

10. The plasma collected by Automated is intended, used or sold by Automated solely as source material for further manufacture into pharmaceutical products.

11. The United States Food and Drug Administration ("FDA") of the United States Department of Health and Human Services has issued regulations, contained in 21 CFR Subchapter F - Biologics, which establish, *inter alia*, standards governing, and procedures for the inspection of, facilities engaging in the process of plasmapheresis.

12. In particular, 21 CFR Part 601 sets forth the prerequisites to, and the procedure to be followed in, obtaining both

"establishment" and "product" licenses; 21 CFR Part 606 sets forth regulations pertaining to good practices for the manufacturing of blood and blood components; 21 CFR Part 607 requires establishment registration and product listing for manufacturers of human blood and blood products; and 21 CFR Part 640 sets forth additional standards for human blood and blood products.

13. Automated is subject to and in compliance with the requirements set forth in the FDA regulations contained in 21 CFR Subchapter F - Biologics.

14. On November 26, 1980, the Commissioners passed Ordinance 80-11 ("Ordinance 80-11") relating to the licensing of "Blood Plasma Donor Centers," and providing that any facility performing plasmapheresis on paid donors must be licensed by the Commissioners, [§1(1)], or face prosecution and penalty, [§2(6)]. Ordinance 80-11 provides further that to obtain the required license, an applicant must first possess a valid permit, [§2(1)]. To obtain the permit, an applicant must furnish to the defendant County Health Department the names and residential and mailing addresses of every employee of his facility, [§2(1)](a)(1)], a list and description of the equipment and facilities of the business, [§2(1)(a)(2)], and "such other information deemed necessary" by the County Health Department, [§2(1)(a)(3)]. In addition, the applicant must allow the County Health Department reasonable and continuing access to the facility for purposes of inspection [§2(1)(a)(4)]. The County Health Department must then forward all of the information provided by the applicant to the Commissioners, "together with the recommendation of the...County Health Department and other pertinent information deemed advisable," [§2(3)]. The Commissioners then, upon notice to the applicant and to the County Health Department, shall, in an open, public meeting, issue or deny the permit or continue the matter for just cause, [§2(3)]. A copy of Ordinance 80-11 is attached to this Complaint as Exhibit "A" and made a part hereof.

15. On November 26, 1980, the Commissioners passed Ordinance 80-12 ("Ordinance 80-12") relating to the identification of paid plasma donors, and providing for record keeping and reporting of information by plasmapheresis facilities to the County Health Department. Ordinance 80-12 provides that any person desiring to undergo plasmapheresis for compensation (a

"Commercial Blood Plasma Vendor") at a facility located within Hillsborough County must first apply to the County Health Department for a "plasma vendor identification number" and a "plasma vendor identification card" good for one plasmapheresis facility only, the name of which shall appear on the face of the identification card, [§4]. Ordinance 80-12 provides further that a plasmapheresis facility may perform the plasmapheresis procedure only after the "Commercial Blood Plasma Vendor" has presented his valid identification card, [§6(A)], the facility has ascertained that the "Vendor" has not participated in the procedure in excess of the standards set forth for amounts of blood removed within particular time periods, [§6(C)], the "Vendor" has been examined by a physician and has been issued a certificate of good health as required by the FDA, [§6(D)], and the facility has performed a "breath analysis" on the "Vendor" immediately prior to the extraction and has determined that the "Vendor's" blood does not contain alcohol in excess of .07 percent weight per volume, [§7]. Ordinance 80-12 provides further that each plasmapheresis facility must maintain upon its premises "such testing materials, equipment, supplies and personnel as are approved by the [County Health Department]" for performing breath analysis, [§7]. Ordinance 80-12 requires further that each plasmapheresis facility report daily to the County Health Department the following information for each Vendor on whom the procedure was performed that day: name, address, age, weight, height, sex, plasma vendor identification number, the results of the breath analysis, the results of testing for hepatitis, the amount of whole blood removed, the proportion of blood cells returned, the current hematocrit value, and "any other identifying information as the [County Health] Department may deem necessary," [§6(A) and (B)]. Ordinance 80-12 provides further that each facility shall pay a fee, assessed by the County Health Department and based on the number of procedures performed by the facility, for the purpose of paying the County Health Department's expenses in implementing and maintaining the Commercial Blood Plasma Vendor Identification System, [§6(F)]. Ordinance 80-12 provides further that the County Health Department may make periodic inspections of each facility to determine the existence of any violations of the Ordinance, [§10]. If a violation is found, the Director of the Department may serve upon the facility a citation setting forth the violation and establishing a deadline for its correction, [§11(B)(1)], or the Director may initiate judicial action to enjoin the violation as a nuisance, [§11(B)(3)]. A copy of Ordinance

80-12 is attached to this Complaint as Exhibit "B" and made a part hereof.

16. On or about March 11, 1981, the Commissioners adopted Rules and Regulations Pursuant to Ordinance 80-12 ("regulations"). These regulations require that a person applying for a Commercial Blood Plasma Vendor Identification Card must supply to the County Health Department, *inter alia*, an "affidavit, signed by the applicant and notarized, stating that said applicant has not been detained or treated for acute or chronic alcoholism during the preceding twelve months," [§2(C)]. The regulations require further that "alcohol level testing . . . shall be performed by a qualified operator using a model #900 Smith and Wesson breath analyzer or equipment of equal quality," [§4]. The regulations provide further that duly authorized representatives of the Director of the County Health Department will inspect each plasmapheresis facility "not less than once annually," [§5]. The regulations further provide that in the event it is deemed necessary by "a physician" in the interests of public health, the "County Health Department may require specific tests [to be performed on potential donors] in addition to those reported [sic] and/or an independent physical examination by a physician other than the physician issuing the applicant's Certificate of Good Health," [§6]. The regulations provide further that the "fee" for administration and maintenance of the Commercial Blood Plasma Vendor Identification system to be paid by each plasmapheresis facility shall be the sum of one dollar ($1.00) for each plasmapheresis procedure performed, [§3(C)]. A copy of the regulations are attached to this Complaint as Exhibit "C" and made a part hereof.

COUNT I

(Federal Preemption)

17. Automated repeats and realleges each and every allegation set forth in paragraphs 1 through 16 hereof.

18. The FDA regulations contained in 21 CFR Subpart F require Automated to obtain a license for its establishment and for its product, to register its establishment and to list its product, to meet specified standards with respect to personnel, facilities, and equipment, to maintain extensive written standard operating procedures, to compile voluminous records and to report

specified information to the FDA, to permit inspections by officials of the FDA, to determine the suitability of donors by means of "medical history, tests and such physical examination as appears necessary to [a] qualified licensed physician" prior to performing the procedure, to reject any donor who "appears to be under the influence of any drug, [or] alcohol" or who appears unsuitable for other reasons, to establish a donor identification system, and to obtain each donor's written informed consent.

19. Ordinance 80-11, Ordinance 80-12, and the regulations thereunder purport to regulate subject matter preempted by federal laws and regulations, in particular those regulations contained in 21 CFR Subchapter F.

20. Ordinance 80-11, Ordinance 80-12, and the regulations thereunder are unconstitutional and invalid under the Commerce Clause of the United States Constitution, U.S. Const. art. I, §8, cl. 3, and the Supremacy Clause of the United States Constitution, U.S. Const. art. VI, cl. 2.

COUNT II

(Impermissible Burden on Interstate Commerce)

21. Automated repeats and realleges each and every allegation set forth in paragraphs 1 through 20 hereof.

22. Ordinances 80-11 and 80-12 and the regulations thereunder subject Automated to additional, burdensome and inconsistent or potentially inconsistent requirements regarding licensing, facilities, the compiling and reporting of information, the identification of donors, and the determination of donor suitability. Pursuant to Ordinances 80-11 and 80-12, and the regulations thereunder, Automated must now procure a county permit and license for its facility as well as federal licenses for, and registrations of, its establishment and its product, it must be subject to duplicative and potentially inconsistent standards regarding its facility and equipment, it is subject to duplicative and potentially inconsistent compilation and reporting requirements, and it is subject to inconsistent requirements regarding the determination of donor suitability.

23. The effect of Ordinances 80-11 and 80-12 and the regulations thereunder, by imposing upon Automated extremely

expensive, time consuming, duplicative and unnecessary requirements, will be to decrease dramatically the ability of Automated to collect human plasma for further manufacture into various pharmaceutical products, and will therefore decrease dramatically the availability of these pharmaceutical products manufactured in part from human plasma collected by Automated.

24. These local ordinances and regulations, adopted ostensibly to safeguard the health in Hillsborough County, impose an indirect burden on interstate commerce which is not justified by local need. The federal regulations contained in 21 CFR Subchapter F impose requirements, standards and procedures sufficient to safeguard the health of donors, thus already effecting the local interest as well as the national interest by means of a single set of regulations.

25. Ordinance 80-11, Ordinance 80-12, and the regulations are unconstitutional and invalid under the Commerce Clause of the United States Constitution, U.S. Const. art. I, §8, cl. 3, and the Supremacy Clause of the United States Constitution, U.S. Const. art. VI, cl. 2.

COUNT III

(Deprivation of Rights, Privileges and Immunities)

26. Automated repeats and realleges each and every allegation set forth in paragraphs 1 through 25 thereof.

27. Section 6(F) of Ordinance 80-12, and §3(C) of the regulations require that Automated pay to the County Health Department the sum of one dollar ($1.00) for each plasmapheresis procedure performed.

28. The amount specified is wholly arbitrary and excessive relative to the actual expense which will reasonably be incurred by the County Health Department.

29. The amount specified represents a substantial portion of Automated's income and is a major burden on the survival capability of Automated's business.

30. The acts, omissions and threatened acts on the part of

the County, the Commissioners, and the County Health Department complained of herein constitute a deprivation, under color of state law, of Automated's rights, privileges and immunities secured by the Constitution and laws of the United States within the meaning of 28 U.S.C. §1343(3) and 42 U.S.C. §1983.

COUNT IV

(Deprivation of Equal Protection)

31. Automated repeats and realleges each and every allegation set forth in paragraphs 1 through 30 hereof.

32. Ordinances 80-11 and 80-12 and the regulations arbitrarily apply only to establishments which perform plasmapheresis on paid donors. There is no rational basis for discriminating between such establishments, of which Automated is one, and similar establishments which perform plasmapheresis on uncompensated donors, or those which extract whole blood from donors whether compensated or not.

33. The acts, omissions and threatened acts on the part of the County, the Commissioners and the County Health Department complained of herein, constitute a denial of the equal protection of law in violation of the Fourteenth Amendment to the Constitution of the United States of America.

COUNT V

(Unlawful delegation of police power)

34. Automated repeats and realleges each and every allegation set forth in paragraphs 1 through 33 hereof.

35. Ordinance 80-11 makes the obtaining of a license and permit to operate a plasmapheresis facility conditional upon an applicant's furnishing to the County Health Department unspecified "information deemed necessary" by the County Health Department [§2(1)(a)(3)]. The County Health Department then forwards to the Commissioners its "recommendation" and "other pertinent information deem advisable", [§2(3)]. The Commissioners then have the power to refuse to grant a permit and license on the basis of the County Health Department's information and recommendation, [§2(3)], and anyone engaging

in the operation of a plasmapheresis facility without the required license is subject to prosecution and punishment, [§2(6)].

36. Sections 2(1)(a)(3) and 2(3) of Ordinance 80-11 lack sufficient guidelines to limit the County Health Department's exercise of discretion, they fail to establish standards and tests for the acts of the County Health Department, and they allow the County Health Department to act arbitrarily, capriciously, and with absolute discretion in deciding what additional, unspecified information will be required to be submitted by some or all permit applicants, and in deciding what additional, unspecified information will be forwarded to the Commissioners together with the County Health Department's recommendation regarding a permit application.

37. Sections 2(1)(a)(3) and 2(3) of Ordinance 80-11 constitute unlawful delegations of the police power and of the legislative authority granted to the County and to the Commissioners by Fla. Stat. §381.101.

COUNT VI

(Deprivation of Due Process)

38. Automated repeats and realleges each and every allegation set forth in paragraphs 1 through 37 hereof.

39. Sections 2(1)(a)(3) and 2(3) of Ordinance 80-11 are vague, indefinite and uncertain, they fail to give potential applicants a reasonable opportunity to know what is required, and they fail to provide explicit standards in order to prevent arbitrary and discriminatory decisions with respect to the grant or denial of applications.

40. Sections 2(1)(a)(3) and 2(3) of Ordinance 80-11 violate the potential permit and license applicant's right to due process of law guaranteed by the Fifth and Fourteenth Amendments to the Constitution of the United States and by the Florida Constitution.

COUNT VII

(Unlawful delegation of police power)

41. Automated repeats and realleges each and every allegation set forth in paragraphs 1 through 40 hereof.

42. Ordinance 80-12 requires that each plasmapheresis facility report daily to the County Health Department certain specified information as well as "any other identifying information as the [County Health] Department may deem necessary," [§6(a)(9)]. The County Health Department is empowered to give notice of any act or condition which it deems to be in violation of Ordinance 80-12, [§11], and anyone convicted of a violation of Ordinance 80-12 is punishable by a fine of up to $500 or by imprisonment of up to 60 days or both, [§14].

43. Section 6(A)(9) of Ordinance 80-12 lacks sufficient guidelines to limit the County Health Department's exercise of discretion, it fails to establish standards and tests for the acts of the County Health Department, and it allows the County Health Department to act arbitrarily, capriciously and with absolute discretion in deciding what additional, unspecified information will be required to be submitted by some or all permit applicants, and in deciding what additional, unspecified information will be required to be submitted by some or all plasmapheresis facilities.

44. Section 6(A)(9) of Ordinance 80-12 constitutes an unlawful delegation of the police power and of the legislative authority granted to the County and to the Commissioners by Fla. Stat. §381.101.

COUNT VIII

(Deprivation of Due Process)

45. Automated repeats and realleges each and every allegation set forth in paragraphs 1 through 44 hereof.

46. Section 6(A)(9) of Ordinance 80-12 is vague, indefinite and uncertain, it fails to give facility operators a reasonable opportunity to know what is required, and it fails to provide ex-

plicit standards in order to prevent arbitrary and discriminatory enforcement of the ordinance.

47. Section 6(A)(9) of Ordinance 80-12 violates the facility operator's right to due process of law guaranteed by the Fifth and Fourteenth Amendments to the Constitution of the United States and by the Florida Constitution.

COUNT IX

(County Health Department acts in excess of its authority)

48. Automated repeats and realleges each and every allegation set forth in paragraphs 1 through 47 hereof.

49. Section 6 of the regulations provides that the County Health Department may, if it is deemed necessary by "a physician," "require specific tests [to be performed on potential donors] in addition to those" required by Ordinance 80-12, and may require "an independent physical examination by a physician other than the physician issuing the applicant's Certificate of Good Health."

50. In asserting that it has the authority to require additional tests and physical examinations, the County Health Department is acting in excess of the authority granted to it under Ordinance 80-12 or the laws of the State of Florida by which the County Health Department was created and exists, and the County Health Department is asserting authority that is not granted to it under any law, statute, regulation or ordinance of the County, the State of Florida, or of the United States.

COUNT X

(County Health Department acts in excess of its authority)

51. Automated repeats and realleges each and every allegation set forth in paragraphs 1 through 50 hereof.

52. Section 2(C) of the regulations requires that an applicant for a Commercial Blood Plasma Identification card submit to the County Health Department "an affidavit, signed...and notarized, stating that said applicant has not been detained or treated for acute or chronic alcoholism during the preceding twelve months."

53. In asserting that it has the authority to require such an affidavit, the County Health Department is acting beyond and in excess of the authority granted to it under Ordinance 80-12 or the laws of the State of Florida by which the County Health Department was created and exists, and the County Health Department is asserting authority that is not granted to it under any law, statute, regulation or ordinance of the County, the State of Florida, or of the United States.

COUNT XI

(Deprivation of Due Process)

54. Automated repeats and realleges each and every allegation set forth in paragraphs 1 through 53 hereof.

55. The word "detained" as used in §2(C) of the regulations is vague, ambiguous, uncertain and indefinite, in that no particular type of detention is specified.

56. In requiring such an affidavit, §2(C) of the County Health Department's regulations violates the potential donor's right to due process of law guaranteed by the Fifth and Fourteenth Amendments to the Constitution of the United States and by the Florida Constitution.

COUNT XII

(The Commissioners act in excess of their statutory power)

57. Automated repeats and realleges each and every allegation set forth in paragraphs 1 through 56 hereof.

58. The Commissioners, in enacting Ordinance 80-11, are acting beyond and in excess of the authority granted to them under Fla. Stat. §381.101 and §381.031(1)(h), and the Commissioners are asserting an authority that is not granted to them under any law, statute, regulation, or ordinance of the State of Florida or of the United States.

WHEREFORE, Automated demands judgment against the defendants as follows:

A. With regard to COUNT I, a declaratory judgment that

the subject matter of Ordinances 80-11 and 80-12 and the regulations thereunder is preempted by federal law and regulations, in particular those regulations contained in 21 CFR Subchapter F, and that Ordinances 80-11 and 80-12 and the regulations thereunder violate the Commerce and Supremacy Clauses of the Constitution of the United States and are therefore wholly without force and effect, illegal, null and void, and unconstitutional, and a preliminary and permanent injunction preventing the County and County Health Department from enforcing or attempting or threatening to enforce said Ordinances or regulations;

B. With regard to COUNT II, a declaratory judgment that Ordinances 80-11 and 80-12 and the regulations thereunder constitute an impermissible burden on interstate commerce not warranted or justified by legitimate local need, and that Ordinances 80-11 and 80-12 and the regulations thereunder violate the Commerce and Supremacy Clauses of the Constitution of the United States and are therefore wholly without force and effect, illegal, null and void, and unconstitutional, and a preliminary and permanent injunction preventing the County and County Health Department from enforcing or attempting or threatening to enforce said Ordinances or regulations;

C. With regard to COUNT III, a declaratory judgment that the requirement in §6(F) of Ordinance 80-12, and §3(C) of the regulations, that Automated pay to the County Health Department the sum of one dollar ($1.00) for each plasmapheresis procedure performed is wholly arbitrary, excessive and constitutes a deprivation, under color of state law, of Automated's rights, privileges and immunities secured by the Constitution and laws of the United States within the meaning of 28 U.S.C. §1343(3) and 42 U.S.C. §1983, and that §6(F) of Ordinance 80-12 and §3(C) of the regulations are therefore wholly without force and effect, illegal, null and void, and unconstitutional, and a preliminary and permanent injunction preventing the County and County Health Department from enforcing or attempting or threatening to enforce said sections of Ordinance 80-12 and the regulations;

D. With regard to COUNT IV, a declaratory judgment that Ordinances 80-11 and 80-12 and the regulations constitute a denial of Automated's right to equal protection of the law in violation of the Fourteenth Amendment to the Constitution of

the United States, and are therefore wholly without force and effect, illegal, null and void, and unconstitutional, and a preliminary and permanent injunction preventing the County and County Health Department from enforcing or attempting or threatening to enforce said Ordinances or regulations;

E. With regard to COUNT V, a declaratory judgment that Sections 2(1)(a)(3) and 2(3) of Ordinance 80-11 constitute unlawful delegations of the police power and of the authority granted to the County and Commissioners by Fla. Stat. §381.101, and are therefore wholly without force and effect, illegal, null and void, and unconstitutional, and a preliminary and permanent injunction preventing the County and County Health Department from enforcing or attempting or threatening to enforce said sections of Ordinance 80-11;

F. With regard to COUNT VI, a declaratory judgment that Sections 2(1)(a)(3) and 2(3) of Ordinance 80-11 are vague, indefinite, uncertain and constitute a denial of Automated's right to due process of law in violation of the Fifth and Fourteenth Amendments to the Constitution of the United States and of the Florida Constitution, and are therefore wholly without force and effect, illegal, null and void, and unconstitutional, and a preliminary and permanent injunction preventing the County and County Health Department from enforcing or attempting or threatening to enforce sections 2(1)(a)(3) and 2(3) of Ordinance 80-11;

G. With regard to COUNT VII, a declaratory judgment that section 6(A)(9) of Ordinance 80-12 constitutes an unlawful delegation of the police power and of the authority granted to the County and Commissioners by Fla. Stat. §381.101, and is therefore wholly without force and effect, illegal, null and void, and unconstitutional, and a preliminary and permanent injunction preventing the County and County Health Department from enforcing or attempting or threatening to enforce section §6(A)(9) of Ordinance 80-12;

H. With regard to COUNT VIII, a declaratory judgment that section 6(A)(9) of Ordinance 80-12 is vague, indefinite, uncertain and constitutes a denial of due process of law in violation of the Fifth and Fourteenth Amendments to the Constitution of the United States and of the Florida Constitution, and is therefore wholly without force and effect, illegal, null and void,

and unconstitutional, and a preliminary injunction preventing the County and County Health Department from enforcing or attempting or threatening to enforce section 6(A)(9) of Ordinance 80-12;

I. With regard to COUNT IX, a declaratory judgment that §6 of the regulations issued by the County Health Department is beyond and in excess of the authority granted to the County Health Department by Ordinance 80-12, and is therefore wholly without force and effect, illegal, null and void, and unconstitutional, and a preliminary and permanent injunction preventing the County and County Health Department from enforcing or attempting or threatening to enforce section 6 of the regulations;

J. With regard to COUNT X, a declaratory judgment that §2(C) of the regulations issued by the County Health Department are beyond and in excess of the authority granted to the County Health Department by Ordinance 80-12, and is therefore wholly without force and effect, illegal, null and void, and unconstitutional, and a preliminary and permanent injunction preventing the County and County Health Department from enforcing or attempting or threatening to enforce section 2(C) of the regulations;

K. With regard to COUNT XI, a declaratory judgment that the use of the word "detained" in §2(C) of the regulations is vague, ambiguous, uncertain and indefinite, and constitutes a denial of the potential donor's right to due process of law, all in violation of the Fifth and Fourteenth Amendments to the Constitution of the United States and of the Florida Constitution, and is therefore wholly without force and effect, illegal, null and void, and unconstitutional, and a preliminary and permanent injunction preventing the County and County Health Department from enforcing or attempting or threatening to enforce §2(C) of the regulations;

L. With regard to COUNT XII, a declaratory judgment that in enacting Ordinance 80-11, the Commissioners acted beyond and in excess of their statutory authority, and that Ordinance 80-11 is therefore wholly without force and effect, illegal, null and void, and unconstitutional, and a preliminary and permanent injunction preventing the County and County Health Department from enforcing or attempting or threatening to enforce Ordinance 80-11;

M. Such other and further relief as may to this Court seem just and proper.

Dated: December 14, 1981

GOLDSTEIN GOLDMAN KESSLER
& UNDERBERG
Attorneys for Automated Medical
Laboratories, Inc.

By:_____
Larry A. Stumpf
One Biscayne Tower, Suite 1740
Two South Biscayne Boulevard
Miami, Florida 33131
(305) 358-4930

Exhibit A 11/26/80

ORDINANCE #80-11

AN ORDINANCE AMENDING THE HILLSBOROUGH COUNTY OCCUPATIONAL LICENSE ORDINANCE #80-6; PROVIDING A SPECIFIC CLASSIFICATION FOR BLOOD PLASMA DONOR CENTERS AND SETTING THE OCCUPATIONAL LICENSE TAX AT $225.00; PROVIDING FOR A PERMIT, AND PROVIDING AN EFFECTIVE DATE

Section 1. Hillsborough County Ordinance 80-6 is amended to add Section 56.01 to read as follows:

Section 56.01 BLOOD PLASMA DONOR CENTERS

(1) Every person or association of persons conducting, carrying on or otherwise engaging in the business (occupation) of a Blood Plasma Donor Center as defined below, shall pay a license tax of $225.00.

(2) "Blood Plasma Donor Center" is defined as any facility, laboratory, or place of business which performs the procedure known as "plasmapheresis" on commercial Blood Plasma Vendors and which compensates said Blood Plasma Vendors by payment of money or other thing of value.

Section 2. Hillsborough County Ordinance 80-6 is amended to add Section 57.01 to read as follows:

Secton 57.01 — BLOOD PLASMA DONOR CENTERS; COUNTY PERMIT REQUIRED; PENALTY —

(1) No license to engage in the occupation of a Blood Plasma Donor Center or any other business entity for which a license is required by Section 56.01 of this Ordinance, shall be issued to any person or association of persons not possessing a valid permit issued by the Hillsborough County Board of County Commissioners (Board). Said permit shall be issued in triplicate with the original being given to the applicant, one copy being retained by the Hillsborough County Health Department, and one copy being retained by the Tax Collector. All permits and licenses issued under the provisions of this Ordinance shall be non-transferable. No permit shall be issued by the Board until the following conditions have been fulfilled:

(a) The applicant for the permit has:

1. Furnished the Hillsborough County Health Department (upon forms provided) with the name and mailing and residential addresses for all non-owner and owner personnel employed with the place of business for which the related license tax is applicable pursuant to Section 56.01 of this Ordinance.

2. Furnished to the Hillsborough County Health

Department (upon forms provided) a list and description of the equipment and facilities of the place of business for which related license tax is applicable pursuant to Section 56.01 of this Ordinance.

3. Furnished to the Hillsborough County Health Department (upon forms provided) such other information as deemed necessary by the Hillsborough County Health Department.

4. Allowed the Hillsborough County Health Department reasonable and continuing access to the premises of the Blood Plasma Donor Center or other business entity concerned with the permit sought by the applicant; said access being granted for purposes of allowing the Hillsborough County Health Department opportunity to inspect the premises.

(2) The possessor of any permit issued by the Board shall, within thirty (30) days of an event or occurrence that causes a change to the information given to the Hillsborough County Health Department pursuant to sub-sections 57.01(1)(a)1, 57.01(1)(a)2, and 57.01(1)(a)3 of this Ordinance, advise the Hillsborough County Health Department (in writing) of such change.

(3) The Hillsborough County Health Department shall, within fifteen (15) days of receiving a completed application for a permit as described by this Section, forward to the Board all such information furnished by the permit applicant; together with the recommendation of the Hillsborough County Health Department and other pertinent information deemed advisable. The Board shall consider the information submitted to it in open, public meeting after notice to the permit applicant and the Hillsborough County Health Department; whereupon the Board shall either issue the permit, continue the matter for just cause, or deny the permit.

(4) Blood Plasma Donor Centers or other business entities issued a permit pursuant to the provisions of this Section shall automatically be re-permitted annually by the Board unless such re-permitting is denied by the Board for just cause after notice and opportunity to be heard. The County Tax Collector shall be notified when re-permitting is denied by the Board.

(5) Every licensee comprehended by Section 56.01 of this Ordinance shall at all times while engaging in the occupation for which licensed, display at the applicable place of business both the license thereby required and the permit required by this Section. Failure or refusal to do so shall be prima facie evidence of engaging in such occupation without a license.

(6) Anyone engaging in any occupation comprehended by Section 56.01 of this Ordinance without a license and the permit required by this Section or who shall obtain any such permit or license by fraud or deceit shall, be subject to prosecution and punishment as described in Section 7.02 of this Ordinance.

Section 3. This Ordinance shall become effective immediately upon acknowledgement from the Secretary of State that it has been properly filed as required by law.

STATE OF FLORIDA)
COUNTY OF HILLSBOROUGH)

I, JAMES F. TAYLOR, Clerk of the Circuit Court and Ex Officio Clerk of the Board of County Commissioners of Hillsborough County, Florida, do hereby certify that the above and foregoing is a true and correct copy of an Ordinance adopted by the Board in its regular meeting of November 26, 1980, as the same appears of record in Minute Book 76 of the Public Records of Hillsborough County, Florida.

WITNESS my hand and official seal this 5th day of December, 1980.

JAMES F. TAYLOR, JR., CLERK
BY: _____
Deputy Clerk

Exhibit B 11/26/80

ORDINANCE #80-12

AN ORDINANCE OF HILLSBOROUGH COUNTY, FLORIDA; RELATING TO IDENTIFICATION OF COMMERCIAL BLOOD PLASMA VENDORS: DEFINING TERMS; REQUIRING BLOOD PLASMA VENDOR IDENTIFICATION CARDS; ESTABLISHING PROCEDURES FOR OBTAINING CARDS; PROVIDING FOR RECORD KEEPING AND REPORTING; SETTING FEES; REQUIRING BREATH ANALYSIS; REQUIRING REPORTING OF COMMUNICABLE DISEASE; PROVIDING FOR ADMINISTRATION; PROVIDING FOR ENFORCEMENT AND INSPECTION; REQUIRING NOTICE; SPECIFYING PENALTY FOR VIOLATIONS; PROVIDING FOR SEVERABILITY; PROVIDING AN EFFECTIVE DATE.

WHEREAS, Section 125.01(1)(w), Florida Statutes allows the Board of County Commissioners of Hillsborough County, Florida, to perform any acts not inconsistent with law which are in the common interest of the people of the County, and exercise all powers and privileges not specifically prohibited by law; and

WHEREAS, Section 125.01(1)(t), Florida Statutes allows the Board of County Commissioners of Hillsborough County, Florida to adopt ordinances necessary for the exercise of its power; and

WHEREAS, the Hillsborough County Board of County Commissioners finds and determines that the interests of the public health mandate the monitoring of the plasmapheresis procedure within Hillsborough County; and

WHEREAS, Section 381.311, Florida Statutes requires local health officials to enforce provisions of local ordinance relating to the public health.

NOW, THEREFORE, BE IT ORDAINED BY THE BOARD OF COUNTY COMMISSIONERS OF HILLSBOROUGH COUNTY, FLORIDA, IN REGULAR MEETING ASSEMBLED THIS _____ DAY OF _____, 1980.

Section 1. Short Title — This ordinance shall be known as the "Commercial Blood Plasma Vendor Identification Ordinance".

Section 2. Statement of Purpose — The purpose of this Ordinance is to provide a system for the registration and identification of and the gathering of medical data applicable to Commercial Blood Plasma Vendors as being in the common interest

of the health of the people of Hillsborough County.

Section 3. Definitions

(A) "Commercial Blood Plasma Vendor" is defined as an individual who sells, barters, or exchanges for monetary consideration, the liquid portion of his or her blood (plasma), through the plasmapheresis process.

(B) "Plasmapheresis" is defined as the procedure whereby whole blood is removed from a Commercial Blood Plasma Vendor by venipuncture (or phlebotomy) the plasma is separated therefrom, and the blood cells returned to the Vendor.

(C) "Plasmapheresis Facility" is defined as any facility, laboratory, or place of business where Commercial Blood Plasma Vendors participate in the plasmapheresis process.

(D) "Department" is defined as the Hillsborough County Health Department.

Section 4. Plasma Donor Identification Card. All Commercial Blood Plasma Vendors within Hillsborough County are required to obtain a valid plasma vendor identification card from the Department. The card shall contain identifying information, as required by the Department, and a number, unique to the Vendor. Only one (1) card and one (1) number shall be issued to each Vendor. The identification card shall be good for one (1) plasmapheresis facility only, the name of which shall appear on the face of the identification card.

Section 5. Procedure

(A) Each prospective Commercial Blood Plasma Vendor shall, before undergoing plasmapheresis, make application to the Department, on a form to be provided by the Department, for a plasma vendor identification number and a plasma vendor identification card. The Commercial Blood Plasma Vendor must provide such identifying information as is deemed necessary by the Department and shall tender to the Department a fee of no more than ten dollars ($10.00) which fee shall fairly reflect the Department's costs for issuance of the plasma vendor identification card. Identification cards issued under the provisions of this Ordinance shall be valid for six (6) months from the date of issue.

(B) In the event a plasma vendor identification card is lost, stolen, or mutilated, a duplicate card will be issued, which card shall be valid for the same period as the original card, and shall only be good for the same plasmapheresis facility as the original card. The fee for such duplicate shall be no more than three dollars ($3.00).

Section 6. Record-keeping

(A) No plasmapheresis facility within Hillsborough County may perform the plasmapheresis process on a Commercial Blood Plasma Vendor until said Vendor presents the plasmapheresis facility with a valid plasma Vendor identification card as required by Section 4 of this Ordinance. The plasmapheresis facility shall keep accurate records of each plasmapheresis procedure performed by it, which shall include:

(1) The date of the plasmapheresis procedure;
(2) The name, address, age, weight, height and sex of the Vendor;
(3) The plasma Vendor identification number of the Vendor;
(4) The results of breath analysis of the Vendor as required by Section 7 of this Ordinance;
(5) The amount of whole blood, not including anticoagulant, removed from the Vendor during the plasmapheresis procedure;
(6) The proportion of the blood cells successfully returned to the Vendor at the time of each procedure;
(7) The results of testing for hepatitis;
(8) The current hematocrit value
(9) Any other identifying information as the Department may deem necessary.

(B) All plasmapheresis facilities within Hillsborough County shall provide the aforementioned information daily to the Department, in writing, who shall compile and maintain such information and give prompt notification of any violation of this Ordinance or of the rules and regulations promulgated hereto.

(C) Prior to beginning the plasmapheresis procedure upon any Commercial Blood Plasma Vendor, the plasmapheresis facility shall ascertain that said Vendor has not participated in the plasmapheresis procedure in excess of the amounts listed below within the times indicated:

(1) The amount of whole blood, not including anticoagulant, removed from a Vendor during the plasmapheresis procedure in any forty-eight (48) hour period shall not exceed one thousand (1,000) milliliters unless the Vendor's weight is one hundred seventy-five (175) pounds or greater, in which case the amount of whole blood, not including anticoagulant removed from the Vendor during the plasmapheresis procedure, in any forty-eight (48) hour

period shall not exceed one thousand two hundred (1,200) milliliters.

(2) The amount of whole blood, not including anticoagulant, removed from a Vendor during the plasmapheresis procedure, within a seven-day period shall not exceed two thousand (2,000) milliliters, unless the Vendor's weight is one hundred seventy-five (175) pounds or greater, in which case the amount of whole blood, not including anticoagulant, removed from the Vendor during the plasmapheresis procedure, within a seven-day period shall not exceed two thousand four hundred (2,400) milliliters.

(3) During the plasmapheresis procedure, no more than five hundred (500) milliliters of whole blood shall be removed from a Vendor at one time unless the Vendor's weight is one hundred seventy-five (175) pounds or greater, in which case no more than six hundred (600) milliliters of whole blood shall be removed from the Vendor at one time.

(D) No plasmapheresis facility within Hillsborough County may perform the plasmapheresis process on a Commercial Blod [sic] Plasma Vendor until said Vendor has been examined by a physician and issued a certificate of good health as required by the regulations of the Food and Drug Administration (FDA), of the United States Department of Health and Human Services.

(E) The Department shall keep all records in a manner which protects the rights of individuals to the confidentiality of their medical records. The disclosure of the identity of, or other information relating to Commercial Blood Plasma Vendors is expressly prohibited, except as such disclosure is directly related to and necessary for enforcement of this Ordinance or as is required by law.

(F) The Department shall assess a fee upon each plasmapheresis facility for the purpose of paying the expenses which the Department shall incur, both direct and indirect, in the implementation and maintenance of the Commercial Blood Plasma Vendor Identification System. The fee shall be based upon the number of plasmapheresis procedures performed by the plasmapheresis facility and shall be payable monthly by the facility upon receipt of an invoice from the Department. Said fee shall not exceed the amount of one dollar ($1.00) for each plasmapheresis procedure which has been performed by the facility, and the total of fees collected shall not exceed the cost to the Department of administering and maintaining the Com-

mercial Blood Plasma Vendor identification system.

Section 7. Breath Analysis — It shall be unlawful for any plasmapheresis facility in Hillsborough County to extract whole blood or any of its products from a Commercial Blood Plasma Vendor unless, immediately prior to said extraction, the facility shall analyze the breath of the Commercial Blood Plasma Vendor and determine from such analysis that the blood of the Commercial Blood Plasma Vendor does not contain alcohol in excess of 0.07 per cent, weight per volume. For the purpose of performing the required breath analysis, each plasmapheresis facility in Hillsborough County shall maintain upon the premises thereof such testing materials, equipment, supplies, and personnel as are approved by the Department.

Section 8. Reporting of Communicable Disease — Any plasmapheresis facility or employee thereof who shall discover that the Vendor evidences veneral disease, or other communicable disease shall immediately submit to the Hillsborough County Health Department a confidential report setting forth the nature of the disease and the name, address commercial blood plasma vendor identification number, and other information sufficient to identify and locate the Vendor.

Section 9. Prohibited Acts — It shall be unlawful for any person to obtain or attempt to obtain more than one plasma vendor identification card or more than one plasma vendor identification number, or for any person to attempt to utilize a vendor identification card or vendor identification number of another individual, or for any person to provide false information to a plasmapheresis facility or to the Hillsborough County Health Department in connection with the application for a Vendor identification card or identification number or in connection with any plasmapheresis procedure.

Section 10. Enforcement and Inspection — It shall be the responsibility of the Director of the Hillsborough County Health Department or his duly authorized representative to enforce the provisions of this Ordinance throughout Hillsborough County and the Director may promulgate rules and regulations necessary to carry out the provisions of this Ordinance. The Hillsborough County Health Department may make periodic inspections of each plasmapheresis facility in Hillsborough County for the purpose of determining the existence of any violation of this Ordinance.

Section 11. Denial, Suspension or Revocation of Identification Card.

A. If the Director of the Hillsborough County Health

Department determines that an individual has violated a provision of this Ordinance, he may deny, suspend, or revoke any Vendor identification card or identification number, according to the following criteria:

(1) For a violation by a person who is not a registered Commercial Blood Plasma Vendor, a disqualification of that person from becoming a registered Vendor for a period not exceeding ninety (90) days for each violation.

(2) For the first violation by a registered Commercial Blood Plasma Vendor, suspension of the Vendor identification card and number and all the privileges incident thereto for a period not exceeding ninety (90) days.

(3) For the second violation by a registered Commercial Blood Plasma Vendor, suspension of the Vendor identification card and number and all the privileges incident thereto for a period not exceeding one (1) year.

(4) For the third violation by a registered Commercial Blood Plasma Vendor, suspension of the Donor identification card and number and all the privileges incident thereto for a period not exceeding five (5) years, or permanent revocation of the Vendor identification card and registration number and all the privileges incident thereto.

(B) If the Director of the Hillsborough County Health Department or his designee shall determine that a violation of this Ordinance or of any regulation promulgated hereunder has occurred, the Director may take one or more of the following actions:

(1) Service upon the person or facility in violation of a citation setting forth the violation and establishing a time within which such violation must be corrected.

(2) Initiation of a procedure for the denial, revocation, suspension, limitation, of any Commercial Blood Plasma Vendor identification card.

(3) The initiation of a judicial procedure for injunctive action against any individual or organization violating this ordinance, it being hereby declared that the performance of the plasmapheresis procedure on any Commercial Blood Plasma Vendor in violation of this Ordinance or any regulation promulgated hereunder is a nuisance inimical to the public health, welfare, and safety.

(4) Whenever the Director of the Department shall have determined the existence of a violation of

this Ordinance which constitutes an immediate threat to the health, safety, or welfare of a Commercial Blood Plasma Vendor, a potential recipient of blood or plasma, or the public, and such condition cannot or will not be immediately corrected, the Director of Public Health may order the immediate closing of such plasmapheresis facility and initiate judicial proceedings seeking injunctive relief to accomplish said purpose until such time as the threat is found no longer to exist.

(C) Whenever the Director of the Hillsborough County Health Department or his duly authorized representative believes that there has been a violation of the provisions of this Ordinance, he shall serve notice of such violation in writing to the party responsible for such violation. The notice shall specify the violation and shall be deemed to be properly served and binding upon the party responsible, if a copy is served personally or served by certified mail, or if after diligent search and inquiry the party responsible for the violation cannot be found or served by personal service or certified mail, a copy of the notice is published once during each week for four (4) consecutive weeks in a newspaper of general circulation within Hillsborough County. The newspaper shall meet such requirements as prescribed by law for such purpose. Such notice shall inform the party to whom it is directed of the right to apply to the Hillsborough County Board of County Commissioners for a hearing and review of the matters specified in the notice.

Section 13. Appeal — Any person aggrieved by a decision of the Department made under the provisions of this Ordinance shall have the right to appeal such decision to the Hillsborough County Board of County Commissioners (Board). Said appeal must be in writing and received by the Board no later than ten (10) days from the date of the decision to be reviewed. The Board shall set such appeal for hearing at the earliest possible date, and cause notice thereof to be given to the appellant and the Director of the Hillsborough County Heatlh Department. The Board shall hear and consider all facts material to the appeal and render a decision promptly. The Board may affirm, reverse, or modify the action or decision appealed from providing that the Board shall not take any action which conflicts or nullifies any of the provisions of this Ordinance. The Board shall specifically state in its decision the date by which compliance must be made. The decision of the Board shall be final, and no rehearing or reconsideration shall be considered. Any party aggrieved by any decision of the Board on appeal taken to it, may apply to the Circuit Court of Hillsborough County for a review by writ of certiorari in accordance with the applicable Florida appellate rules.

Section 14. Penalty — A conviction for violation of the provisions of this Ordinance shall be punishable by a fine not to exceed five hundred dollars ($500.00) or by imprisonment in the County jail for a term not to exceed sixty (60) days or both such fine and imprisonment, as provided in Section 125.69, Florida Statutes.

Section 15. Federal Regulations — The regulations of the Commissioner of the Food and Drug Administration of the United States Department of Health and Human Services, as they may be amended from time to time concerning plasmapheresis and source plasma (human) currently appearing at 21 CFR Part 640, Subpart G, Section 640.60 et seq, are here incorporated by reference and shall be a part of this Ordinance as though set forth herein verbatim.

Section 16. Severability — If any section, subsection, sentence, clause, provision or part of this Ordinance shall be held invalid for any reason, the remainder of this Ordinance shall not be affected thereby, but shall remain in full force and effect.

Section 17. Effective Date — This Ordinance shall take effect ninety (90) days after filing with the Secretary of State as provided by law.

STATE OF FLORIDA)
COUNTY OF HILLSBOROUGH)

I, JAMES F. TAYLOR, Clerk of the Circuit Court and Ex Officio Clerk of the Board of County Commissioners of Hillsborough County, Florida, do hereby certify that the above and foregoing is a true and correct copy of an Ordinance adopted by the Board in its regular meeting of November 26, 1980, as the same appears of record in Minute Book 76 of the Public Records of Hillsborough County, Florida.

WITNESS my hand and official seat [sic] this 5th day of December, 1980.

JAMES F. TAYLOR, JR. CLERK
BY: _____
Deputy Clerk

Exhibit C

3/5/81

RULES AND REGULATIONS PURSUANT TO HILLSBOROUGH COUNTY ORDINANCE #80-12

Section 1. — Purpose

These Rules and Regulations are adopted to establish procedures for the monitoring of the plasmapheresis process within Hillsborough County, and the issuance of Commercial Blood Plasma Vendor Identification Cards by the Hillsborough County Health Department, under the Authority of Hillsborough County Ordinance 80-12.

Section 2. — Identification

Before being issued a Commercial Blood Plasma Vendor Identification Card pursuant to Hillsborough County Ordinance 80-12, each applicant shall furnish to the Hillsborough County Health Department:

A. One of the following items of positive identification:
   1. A Social Security card exhibiting the applicant's signature;
   2. A Hillsborough County voter registration card exhibiting the applicant's signature;
   3. A selective service identification card exhibiting the applicant's signature;
   4. A valid driver's license exhibiting the applicant's photograph and signature;
   5. A United States passport exhibiting the applicant's photograph and signature;
   6. Discharge documents from the United States military service exhibiting the applicant's signature.

B. A Certificate of Good Health as required by the regulations of the Food and Drug Administration (F.D.A.) of the United States Department of Health and Human Services and Hillsborough County Ordinance 80-12.

C. An Affidavit, signed by the applicant and notarized, stating that said applicant has not been detained or treated for acute or chronic alcoholism during the preceding twelve months.

Section 3 — Fees

As required by Hillsborough County Ordinance 80-12

A. The fee for issuance of the Commercial Blood Plasma Vendor Identification Card shall be two dollars ($2.00) to be paid by the applicant.

B. The fee for issuance of a duplicate Commercial Blood Plasma Vendor Identification Card, under the provisions of Section 5(B) of Hillsborough County Ordinance 80-12, shall be two dollars ($2.00), to be paid to the applicant.

C. The fee for administration and maintenance of the Commercial Blood Plasma Vendor Identification system under the provisions of Hillsborough County Ordinance 80-12, shall be the sum of one dollar ($1.00), for each plasmapheresis procedure performed, to be paid by the plasmapheresis facility.

Section 4 — Breath Analysis

Alcohol level testing as required by Section 7 of Hillsborough County Ordinance 80-12, shall be performed by a qualified operator using a model 900 Smith and Wesson breath analyzer or equipment of equal quality.

Section 5 — Inspections

Pursuant to Section 10 of Hillsborough County Ordinance 80-12, duly authorized representatives of the Director of Hillsborough County Health Department will inspect each plasmapheresis facility within Hillsborough County not less than once annually. These inspections will be made without prior notice to the plasmapheresis facility. Such inspection shall include records required to be kept by the plasmapheresis facility under Hillsborough County Ordinance 80-12.

Section 6 — Additional Tests

In the event it is deemed necessary by a physician in the interests of the public health, the Hillsborough County Health Department may require specific tests in addition to those reported and/or an independent physical examination by a physician other than the physician issuing the applicant's Certificate of Good Health.

The Hillsborough County Health Department may delay issue of the Commercial Blood Plasma Vendor Identification Card for a period of ten (10) days if deemed necessary for examination testing, or investigative purposes.

Section 7 — Phase-In Period

As of the effective date of Hillsborough County Ordinance 80-12, no plasmapheresis facility within Hillsborough County may perform the plasmapheresis process on a commercial blood plasma vendor until said vendor presents the plasmapheresis facility with a valid Commercial Blood Plasma Vendor Identification Card; provided however, during the period of ninety

(90) days from the date these Rules and Regulations are adopted, each plasmapheresis facility may, nevertheless, perform the plasmapheresis procedure on a non card holder in instance where such commercial blood plasma vendors are vendors who have previously and regularly undergone the plasmapheresis procedure at that particular facility and where such vendors appear on that facility record of current vendors as of the effective date of Hillsborough County Ordinance 80-12.

Section 8 — Falsification of Information

In the case of falsification by a commercial blood plasma vendor of any information required by Hillsborough County Ordinance 80-12, or these Rules and Regulations promulgated pursuant thereto, the Hillsborough County Health department may deny the issuance of or revoke any existing Commercial Blood Plasma Vendor Identification Card of the person falsifying any information.

CERTIFICATION

This is to certify that the foregoing Rules and Regulations were promulgated pursuant to Section 10 of Hillsborough County Ordinance 80-12.

DONALD S. KWALECK, M.D.
Director of Hillsborough
County Health Department

IN THE UNITED STATES DISTRICT COURT
FOR THE MIDDLE DISTRICT OF FLORIDA

CASE NO. 81-1161-CIV-T-WC

AUTOMATED MEDICAL LABORATORIES, INC.,
Plaintiff,

-vs-

HILLSBOROUGH COUNTY, FLORIDA and
HILLSBOROUGH COUNTY HEALTH DEPARTMENT,
Defendants.

FILED March 18, 1982
Tampa, Fla.

ANSWER

COME NOW the Defendants, HILLSBOROUGH COUNTY, FLORIDA and the HILLSBOROUGH COUNTY HEALTH DEPARTMENT, by and through their undersigned attorneys, and file this their Answer to the Complaint filed by Plaintiff, AUTOMATED MEDICAL LABORATORIES, INC., and state that:

1. Admitted.

2. Without knowledge.

3. Admitted.

4. Admitted.

5. Denied.

6. Without knowledge.

7. Without knowledge.

8. Admitted.

9. Without knowledge.

10. Without knowledge.

11. Admitted.

12. Admitted.

13. Without knowledge.

14. Admitted.

15. Admitted.

16. Admitted.

COUNT I

17. Defendants reallege their answers to paragraphs 1 through 16 as stated above.

18. Without knowledge.

19. Denied.

20. Denied.

COUNT II

21. Defendants reallege their answers to paragraphs 1 through 20 as stated above.

22. Defendants deny that the requirements of Ordinances 80-11 and 80-12 and the regulations thereunder are burdensome, inconsistent or potentially inconsistent and Defendants are without knowledge of the remainder of the allegations contained in paragraph 22.

23. Denied.

24. Denied.

25. Denied.

COUNT III

26. Defendants reallege their answers to paragraphs 1 through 25 as stated above.

27. Without knowledge.

28. Denied.

29. Without knowledge.

30. Denied.

COUNT IV

31. Defendants reallege their answers to paragraphs 1 through 30 as stated above.

32. Defendants admit that Ordinances 80-11 and 80-12 and the regulations thereunder apply only to establishments which perform plasmapheresis on paid donors, but Defendants deny the remainder of the allegations contained in paragraph 32.

33. Denied.

COUNT V

34. Defendants reallege their answers to paragraphs 1 through 33 as stated above.

35. Defendants deny that Ordinance 80-11 requires "unspecified" information, but admit the remainder of the allegations contained in paragraph 35.

36. Denied.

37. Denied.

COUNT VI

38. Defendants reallege their answers to paragraphs 1 through 37 as stated above.

39. Denied.

40. Denied.

COUNT VII

41. Defendants reallege their answers to paragraphs 1 through 40 as stated above.

42. Admitted.

43. Denied.

44. Denied.

COUNT VIII

45. Defendants reallege their answers to paragraphs 1 through 44 as stated above.

46. Denied.

47. Denied.

COUNT VIII

48. Defendants reallege their answers to paragraphs 1 through 47 as stated above.

49. Admitted.

50. Denied.

COUNT X

51. Defendants reallege their answers to paragraphs 1 through 50 as stated above.

52. Admitted.

53. Denied.

COUNT XI

54. Defendants reallege their answers to paragraphs 1 through 53 as stated above.

55. Denied.

56. Denied.

COUNT XII

57. Defendants reallege their answers to paragraphs 1 through 56 as stated above.

58. Denied.

WHEREFORE, Defendants having fully answered the allegations contained in the Complaint respectfully pray that this Honorable Court dismiss this cause of action.

Respectfully submitted,

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[Certificate of Service omitted in printing.]

UNITED STATES DISTRICT COURT
MIDDLE DISTRICT OF FLORIDA
TAMPA DIVISION

Case No. 81-1161-Civ-T-WC

AUTOMATED MEDICAL LABORATORIES, INC.,
Plaintiffs,
vs.
HILLSBOROUGH COUNTY, FLORIDA, et al.,
Defendants.

FILED CLERK, U.S. DISTRICT COURT
NOV. 1, 1982
MIDDLE DISTRICT OF FLORIDA, TAMPA, FLORIDA

OPINION

This cause came on before the Court on a non-jury trial on September 16 and 17, 1982. Plaintiff Automated Medical Laboratories, Inc. filed this action against Hillsborough County, Florida and the Hillsborough County Health Department, challenging the constitutionality of Hillsborough County Ordinances 80-11 and 80-12 and the Rules and Regulations promulgated thereunder. The challenged ordinances regulate licensing and operation of paid blood plasma donor centers. Plaintiff sought a declaratory judgment that the ordinances were unlawful and a permanent injunction against enforcement of the legislation.

Plaintiff challenged the ordinances on several grounds. It claimed that federal legislation preempted the local laws, that the local ordinances impermissibly burdened interstate commerce, and that the county ordinances unlawfully deprived Plaintiff of equal protection of the law by regulating only plasma centers that pay donors and not centers where unpaid volunteers donate whole blood. Plaintiff raised several other issues in the pleadings, such as unlawful delegation, violation of rights, privileges and immunities, and violation of due process. Plaintiff did not specifically adduce evidence or address these issues at trial, however, and the Court finds these arguments without merit.

Based on the evidence presented at trial and a review of the exhibits, the Court makes the following findings:

(1) Plaintiff is a Florida corporation that operates, through subsidiary corporations, eight blood plasma centers in the United States, one of which, Tampa Plasma Corporation, is located in Tampa, Hillsborough County, Florida. Plaintiff's plasma centers collect blood plasma from paid donors by plasmapheresis. In a single procedure this process removes whole blood from the donor, removes the plasma from the whole blood, and then returns the red blood cells to the donor. Plaintiff sells the plasma collected to pharmaceutical concerns that manufacture it as a raw material into products such as tetanus vaccine, albumin, and anti-hemophilic factor. Tampa Plasma Corporation collects and sells no whole blood.

(2) When Hillsborough County enacted the challenged ordinances, the Food and Drug Administration of the United States Department of Health and Human Services had issued regulations in 21 C.F.R. Subchapter F - Biologics that established standards and procedures for plasmapheresis operations. The regulations provide for FDA inspection of plasmapheresis facilities, establish standards for personnel and physical plants, necessitate licenses for plasmapheresis products and facilities, and establish human blood product standards, including the means to select suitable plasmapheresis donors.

(3) Hillsborough County Ordinance 80-11 imposes a license fee on plasmapheresis centers. The purpose of Hillsborough County Ordinance 80-12 is "to provide a system for the registration and identification of and the gathering of medical data applicable to Commercial Blood Plasma Vendors as being in the common interest of the health of the people of Hillsborough County." Pertinent provisions include the requirement that all plasma vendors obtain an identification card from the Health Department (at a cost of $2.00 as provided for in the rules and regulations pursuant to the ordinance). The ordinance requires the plasmapheresis centers to keep records of the procedures they perform, including the results of hepatitis testing, and to ascertain that a plasma vendor has not undergone a plasmapheresis procedure within specified time periods. The ordinance prohibits performance of the plasmapheresis procedure on any vendor who has not obtained a certificate of good health after examination by a physician. It imposes a fee, not to exceed

$1.00, for each procedure performed, with a limitation that fees collected shall not exceed the cost of administering and maintaining the identification system. It requires a pre-plasmapheresis breath analysis of each vendor by means of approved equipment, material, and supplies. The ordinance incorporates by reference the FDA regulations as they appear at 21 C.F.R., Subpart G, Section 640.60 et seq.

(4) In conformance with the FDA Regulations, Tampa Plasma Center currently provides its donors with identification cards. These cards are issued by individual centers, however, and plasma centers throughout the county do not cross-check with each other to ascertain whether a vendor has recently undergone plasmapheresis. The prospective vendor must give a medical history and undergo a physical examination, parts of which are performed by the center's non-medical personnel. A physician who has informed the vendor of the possible hazards and has questioned him about his understanding of the procedure accepts or rejects the vendor. After the plasmapheresis procedure is completed, a hepatitis test is performed and the plasma is kept in segregated storage until the center receives the results.

Under the county ordinances, the vendor would be required to obtain a county-wide identification card, which would not be issued prior to performance of a physical exam. The vendor would undergo a hepatitis test prior to registration, and breath analysis for alcohol content would be performed prior to each plasma donation.

(5) At trial, officers of the Plaintiff corporation attempted to establish the cost to Plaintiff of compliance with the ordinances. Their figures, however, were clouded with speculation. Mr. Dennis Healey, for instance, testified about a document he prepared (Exhibit 20) showing estimates of implementation costs. Except for the cost of the new fees, implemented by the Hillsborough County Health Department, the other estimated increased costs were based on Mr. Healey's opinion that the vendor population would decrease by twenty-five percent once the ordinances were enforced, primarily because the cost and inconvenience of obtaining the Health Department identification card would discourage new vendors. Mr. Healey, however, testified to no facts on which he based his opinion.

Plaintiff also encountered difficulty in estimating the increased cost per liter of plasma attributable to the requirement that the plasmapheresis center determine a prospective vendor's blood alcohol content by use of breathalyzer equipment manned by personnel with approved training. Plaintiff estimated that the machine alone would cost about $5,000.00; however, personnel training costs could not be estimated because approved training presently is available only through the Tampa Police Department.

(6) Much of the testimony at trial concerned the intent of the County Commissioners in enacting the ordinances. Plaintiff attempted to demonstrate that the ordinances were enacted in response to the social problems caused by inebriates and vagrants frequenting the area around the plasma centers. Plaintiff argued that the purpose of the regulations was to eliminate plasmapheresis centers from Hillsborough County by imposing severe economic burdens on their operations. Plaintiff failed to prove, however, that the legislative intent was anything other than that articulated in Ordinance 80-12 — to register and to identify vendors and to supplement and extend the federal regulations and their purposes.

(7) Defendants introduced testimony from physicians qualified as experts in the plasmapheresis field as to the need for and beneficial effect of a county-wide system of vendor identification. Under the federal regulations no system monitors the frequency with which individual vendors undergo the plasmapheresis procedure. Because of monetary inducements for undergoing plasmapheresis, vendors may donate plasma too frequently and put themselves in real danger of being overbled. This problem is particularly acute when the vendor is a chronic alcoholic with borderline liver function. The donor identification system will also help to insure the quality of the product in that vendors will be screened for hepatitis before they receive their identification cards, thus eliminating the hazards involved in handling potentially contaminated plasma.

Defendants' medical experts also expressed concern that a vendor under the influence of alcohol may not have sufficient understanding of the nature of the procedure and the risks it entails. The breathalyzer test requirement is intended to solve this problem. Under the federal regulations, however, Automated Laboratories, Inc. has established reliable procedures to screen

out persons under the influence of alcohol at two stages — when they are initially tested by the receptionist and when the physician examines them.

(8) The ordinances in question regulate only plasmapheresis centers that pay vendors. Testimony at trial showed that no whole blood centers in Hillsborough County pay donors. Furthermore, the legislators' concern for the safety of vendors and the quality of the product is applicable only to paid centers. Medical experts testified that plasma vendors have a much higher incidence of hepatitis than voluntary whole blood donors. Also, the problem of overbleeding does not exist among voluntary whole blood donors who have no monetary incentive to make frequent donations.

Based on the foregoing findings of fact the Court makes the following conclusions of law:

(1) Hillsborough County Ordinances 80-11 and 80-12 and the rules and regulations promulgated thereunder are not preempted by federal regulation. "There is neither such actual conflict between the two schemes of regulation that both cannot stand in the same area, nor evidence of a congressional design to preempt the field." *Florida Lime & Avocado Growers, Inc. v. Paul*, 373 U.S. 132, 141 (1963). Plaintiff pointed to language in the Federal Register expressing the purpose of the federal regulations "to assure uniform adherence to the highest attainable standards of of [sic] practice in blood banking, including plasmapheresis and plasma fractionation," 39 Fed.Reg. 18614 (1974); but there is no evidence of express congressional intent to occupy the entire field of assuring high standards of practice in plasmapheresis. Moreover, the comprehensive nature of the federal legislation alone does not imply a congressional intent to preempt. *New York State Dep't. of Social Servs. v. Dublino*, 413 U.S. 405, 415 (1973). Finally, Hillsborough County Ordinances 80-11 and 80-12 supplement rather than conflict with the federal regulations, particularly in the ordinances' emphasis on ensuring vendor safety.

(2) Hillsborough County Ordinances 80-11 and 80-12 and the rules and regulations promulgated thereunder do not deprive Plaintiff of equal protection of the laws. Although the local legislation applies only to paid plasmapheresis centers and not to voluntary whole blood centers, Defendants successfully demon-

strated that there is a rational basis for regulating only the paid plasma centers. Because Plaintiff contends that the ordinances deprive Plaintiff of a property right rather than infringe upon a fundamental personal right, a rational basis for enactment of the statute is sufficient. *New Orleans v. Dukes*, 427 U.S. 297 (1976). This rational basis is evident from the following: vendors tend to sell their plasma more frequently than volunteers donate their whole blood; plasma vendors have a much higher rate of hepatitis than whole blood donors; and no paid whole blood centers exist in Hillsborough County.

(3) Hillsborough County Ordinance 80-11 and the rules and regulations promulgated thereunder do not place an impermissible burden on interstate commerce. Section 7 of Hillsborough County Ordinance 80-12 and Section 4 of the Rules and Regulations Pursuant to Hillsborough County Ordinance 80-12 impermissibly burden interstate commerce. The remainder of Hillsborough County Ordinance 80-12 and the Rules and Regulations Pursuant to Hillsborough County Ordinance 80-12 do not place an impermissible burden on interstate commerce.

The Supreme Court has stated the general rule for determining whether a state or local law is invalid by virtue of its effect on interstate commerce:

> Where the statute regulates evenhandedly to effect a legitimate local public interest, and its effects on interstate commerce are only incidental, it will be upheld unless the burden imposed on such commerce is clearly excessive in relation to putative public benefits. If a legitimate local purpose is found, then the question becomes one of degree. And the extent of the burden that will be tolerated will of course depend on the nature of the local interest involved, and on whether it could be promoted as well with a lesser impact on interstate activities.

Pike v. Bruce Church, Inc., 397 U.S. 137, 142 (1970).

For reasons previously stated, the Court finds that the ordinances regulate evenhandedly and serve a legitimate local purpose. The Court must therefore determine whether the burden, if any, imposed on interstate commerce is clearly excessive in relation to local benefits.

The Plaintiff was unable to demonstrate the total economic impact on it of enforcement of the ordinances. The evidence demonstrated, however, that significant protection for vendors would be assured by the vendor identification system, that the hepatitis pre-test requirement will help insure the quality of the product, and that the license and plasmapheresis fees will pay for the cost to the County of implementing and enforcing the ordinances. Clearly, all of these provisions, which will create some economic burden on the Plaintiff, will significantly benefit the health, safety, and welfare of the citizens of Hillsborough County.

The benefits of the breathalyzer requirement are not so readily apparent, however. Plaintiff demonstrated that the procedures it follows under the federal regulations achieved the same purpose as a breathalyzer test though the subjective evaluation of each potential vendor by the Plaintiff's personnel and physicians. Defendants did not demonstrate that the breathalyzer requirement, which will create a large, albeit precisely undedetermined [sic], economic burden on the Plaintiff, will "effectuate a legitimate public interest" that is not already achieved by Plaintiff's requirement with the federal regulations. Therefore, Section 7 of Hillsborough County Ordinance 80-12 and Section 4 of the Rules and Regulations Pursuant to Hillsborough County Ordinance 80-12 are invalid in that they impose an impermissible burden on interstate commerce.

Judgment will be entered in accordance with this Opinion.

DATED at Tampa, Florida this 1st day of November, 1982.

WILLIAM J. CASTAGNA
UNITED STATES DISTRICT JUDGE

Copies to:

Counsel of Record

UNITED STATES DISTRICT COURT
MIDDLE DISTRICT OF FLORIDA
TAMPA DIVISION

Case No. 81-1161-Civ-T-WC

AUTOMATED MEDICAL LABORATORIES, INC.,
Plaintiffs,
vs.
HILLSBOROUGH COUNTY, FLORIDA, et al.,
Defendants.

FILED CLERK, U.S. DISTRICT COURT
NOV. 1, 1982
MIDDLE DISTRICT OF FLORIDA, TAMPA, FLORIDA

FINAL JUDGMENT

In accordance with the Opinion filed herein this date, it is

ADJUDGED:

Section 7 of Hillsborough County Ordinance 80-12 and Section 4 of the Rules and Regulations Pursuant to Hillsborough County Ordinance 80-12 are invalid in that they impose an impermissible burden on interstate commerce and the Defendants and their agents and employees are hereby enjoined from enforcing or attempting to enforce them.

As to the other claims of Plaintiff Automated Medical Laboratories, Inc., Judgment is entered in favor of the Defendants Hillsborough County, Florida and Hillsborough County Health Department, and Plaintiff shall take nothing.

DATED at Tampa, Florida this 1st day of November, 1982.

WILLIAM J. CASTAGNA
UNITED STATES DISTRICT JUDGE

Copies to:

Counsel of Record

AUTOMATED MEDICAL LABORATORIES, INC.,
Plaintiff-Appellant,
v.
HILLSBOROUGH COUNTY, Florida, and
Hillsborough County Health Department,
Defendants-Appellees.

No. 83-3014.

United States Court of Appeals,
Eleventh Circuit.

Jan. 16, 1984.

Appeal was taken from a judgment of the United States District Court for the Middle District of Florida, William J. Castagna, J., finding that parts of county ordinances regulating collection of blood plasma from paid donors by plasmapheresis were invalid. The Court of Appeals, Tuttle, Senior Circuit Judge, held that ordinances were implicitly preempted by federal regulation, as pervasiveness of federal regulatory scheme made it reasonable to infer that Congress left no room for local ordinances to supplement it, federal interest in plasmapheresis was dominant over any local interest, and enforcement of state law would present serious danger of conflict with administration of federal program.

Affirmed in part, reversed in part.

1. States 4.10
Preemption of state law by federal statute or regulation is not favored in the absence of persuasive reasons. U.S.C.A. Const. Art. 6, cl. 2.

2. States 4.10
Touchstone of a preemption analysis is congressional intent, which may be either express or implied. U.S.C.A. Const. Art, 6, cl. 2.

3. Counties 21½
Health and Environment 33
States 4.12

County ordinances regulating collection of blood plasma from paid donors by plasmapheresis were implicitly preempted by federal regulation, as pervasiveness of federal regulatory scheme made it reasonable to infer that Congress left no room for local ordinances to supplement it, federal interest in plasmapheresis was dominant over any local interest, and enforcement of state law would present serious danger of conflict with administration of federal program. U.S.C.A. Const. Art. 6, cl. 2; Public Health Service Act, §§ 2 et seq., 351, 42 U.S.C.A. §§ 201 et seq., 262; Federal Food, Drug, and Cosmetic Act, §§ 1 et seq., 201(g)(1), 21 U.S.C.A. §§ 301 et seq., 321(g)(1).

Larry A. Stumpf, Miami, Fla., for plaintiff-appellant.

Richard Landfield, Washington, D.C., for amicus Blood Resources Assoc. & FL Assoc. of Plasmapheresis Establishments.

Deolores D. Menendez and Emeline L. [sic] Acton, Tampa, Fla., for defendants-appellees.

Appeal from the United States District Court for the Middle District of Florida.

Before FAY and HENDERSON, Circuit Judges, and TUTTLE, Senior Circuit Judge.

TUTTLE, Senior Circuit Judge:

Appellant Automated Medical Laboratories, Inc. ("Automated") filed a civil action against appellees Hillsborough County, Florida (the "County") and Hillsborough County Health Department (the "Department") in the United States District Court for the Middle District of Florida. Appellant challenged the constitutionality of County Ordinances 80-11 and 80-12 ("County Ordinances") and the rules and regulations promulgated thereunder. Following a nonjury trial, United States District Court Judge William J. Castagna rejected all of Automated's constitutional attacks on the local legislation, including its federal preemption attack, except for the claim that § 7 of Ordinance 80-12 and § 4 of the rules and regulations imposed an impermissible burden on interstate commerce. This Court finds that the County Ordinances are pre-empted by federal regulation. Therefore,

the district court holding that § 7 of Ordinance 80-12 and § 4 of the rules and regulations are invalid is affirmed, and the holding that the remainder of the County Ordinances are valid is reversed.

I. BACKGROUND

Automated is a Florida corporation that operates, through subsidiary corporations, eight blood plasma centers in the United States. One of the centers, Tampa Plasma Corporation ("TPC"), is located in Tampa, Hillsborough County, Florida. Automated's plasma centers collect blood plasma from paid donors by plasmapheresis. Plasmapheresis is a process whereby, during a single procedure, blood is removed from a human donor, the plasma is removed from the whole blood, and the red blood cells are returned to the donor. Automated sells the plasma to pharmaceutical concerns, which use it in the manufacture of pharmaceutical products such as tetanus vaccine, albumin, and anti-hemophilic factor.

Prior to the enactment of the County Ordinances, the Food and Drug Administration of the United States Department of Health and Human Services ("FDA") had issued regulations, which are contained in 21 C.F.R. §§ 600.3-680.26 (1983) (the "federal regulations"), that established standards and procedures for plasmapheresis operations. The federal regulations provide for FDA inspection of plasmapheresis facilities, establish standards for personnel and physical plants, necessitate licenses for plasmapheresis products and facilities, and establish human blood product standards, including the means to select suitable plasmapheresis donors.

In conformance with the federal regulations, TPC selects plasma donors on the basis of medical history, tests, and physical examinations. On each potential donor's initial visit, and at four-month intervals thereafter, TPC's staff physician reviews the candidate's medical history, performs a physical examination, and decides whether to reject or accept the candidate. If the candidate is accepted, the physician explains the plasmapheresis procedure as well as its associated risks and obtains the candidate's written informed consent to having the plasmapheresis procedure performed. In addition to the regularly scheduled staff physician's review and examination, nonmedical employees of TPC, who are trained and supervised by

the staff physician, review the candidate's medical history prior to each donation of plasma. Nonmedical employees also determine, prior to each donation of plasma, that the candidate's weight, body temperature, blood pressure, pulse rate, serum protein, and hematocrit value are within the limits established by the federal regulations.

In conformance with the federal regulations, TPC has established procedures for eliminating from its donor population persons whose plasma could contain hepatitis virus. The staff physician rejects any candidate who has a history of viral hepatitis, a history of addiction to self-injected narcotics, or who has, within the preceding six months, had close contact with anyone having viral hepatitis, undergone major surgery, received whole blood or any human blood derivative known to be a possible source of viral hepatitis, or been tattooed. In addition, TPC sends a sample of each donation of plasma it collects to an outside laboratory operated by another wholly owned subsidiary of Automated to be tested for hepatitis contamination. If a sample is found to be contaminated, TPC destroys the unit of plasma from which the sample was taken and permanently rejects the donor from whom that unit was collected.

TPC has also established procedures for eliminating candidates who have exceeded the volume and frequency limits for plasma donations established in the federal regulations. To monitor the frequency with which a person donates plasma, TPC has established a donor identification system. At the time of a donor's first visit, TPC requires two forms of identification to establish the donor's identity. To identify the donor on subsequent visits, TPC provides the donor with an identification card, to which is affixed the donor's photograph. In addition, TPC establishes for each donor a permanent donor record file, which contains the donor's photograph and signature, as well as descriptive identifying information (address, telephone number, birthday, sex, height, eye and hair color, race, and blood type), written reports of the donor's physical examinations, signed consent forms, and written records documenting every plasma donation made. For each donation, TPC documents the date of donation, the bleed number, the donor's medical history and laboratory test results, and the volume of whole blood and red blood cells returned. By means of a permanent donor record file, TPC can deter any attempted donation which would result in a potential donor subjecting his or her health to risks by exceeding

the amount and frequency limits set forth in the federal regulations.

TPC is not required by the federal regulations to coordinate its donor identification system with that of other plasma centers in the County. If, however, circumstances warrant the checking of a potential donor's identity with another plasmapheresis center, TPC's phlebotomists examine both arms of the potential donor for signs of recent needle marks. Any potential donor who evidences recent needle marks that cannot be attributed to previous donations reflected in his or her permanent donor record file is referred to the staff physician for further evaluation.

The federal regulations provide for the inspection of TPC by an FDA official at least once every two years. The FDA inspection covers all aspects of the condition of TPC's facility, equipment, and records, as well as the methods used by TPC in collecting, processing, testing, storing, and shipping the plasma it collects. During the four years preceding the trial of this action, TPC was inspected approximately six times by the FDA. Those inspections apparently failed to reveal any deficiency in TPC's plasmapheresis operation other than a noisy fan or air conditioner in the staff physician's office, which allegedly made it difficult for one physician to communicate well with potential donors, forms that needed to be reprinted to make them clearly legible, and the observation, contested by TPC at the time of the inspection, that the staff physician had once "checked off" certain parts of a potential donor's physical examination form before actually performing them.

On November 26, 1980, the County adopted Ordinances 80-11 and 80-12. Ordinance 80-11 imposes a license tax and conditions the issuance of a license on, among other things, agreement by the blood plasma donor center to "reasonable and continuing access" by Department personnel for inspections, a public hearing, and continuously updated information regarding the owners, employees, equipment, and facilities.

The stated purpose of Ordinance 80-12 is "to provide a system for the registration and identification of and the gathering of medical data applicable to Commercial Blood Plasma Vendors as being in the common interest of the health of the people of Hillsborough County." On March 5, 1981, the Department issued rules and regulations pursuant to Ordinance 80-12.

Ordinance 80-12 requires that a potential donor must undergo a medical examination and obtain a "certificate of good health" before participating in the plasmapheresis process within the County. The regulations require that a potential donor present that certificate, together with his or her own sworn affidavit stating that he or she has not been detained or treated for acute or chronic alcoholism during the preceding twelve months, to the Department. The Department then issues its own identification card to the potential donor. This identification card permits the potential donor to undergo plasmapheresis for a period of six months only at a single specified plasmapheresis facility located within the County.

Ordinance 80-12 also requires that TPC submit to the Department on a daily basis information as to each plasmapheresis procedure performed, including the following: the date of the procedure; the name, address, age, weight, height, sex, identification number, and current hematocrit value of the donor; the results of the donor's breath analysis; the amount of whole blood removed and the proportion of red cells returned; and the results of testing for hepatitis. Neither the ordinance nor the regulations indicate what use the Department is to make of this information. Ordinance 80-12 and the regulations also require TPC to pay the Department a fee of $1.00 for each plasmapheresis procedure it performs. The purpose of this fee seems to be limited to maintaining the bureaucracy needed to store the information provided by TPC.

Ordinance 80-12 authorizes the Department to inspect TPC periodically, even though the Department apparently employs no qualified inspector. The regulations provide that such inspections shall occur at least annually. Finally, Ordinance 80-12 subjects TPC to criminal sanctions for violation of its provisions.

II. DISCUSSION

The first issue before this Court is whether County Ordinances 80-11 and 80-12 and the rules and regulations promulgated thereunder are pre-empted by the federal scheme.

[1,2] The rationale underlying the pre-emption doctrine is that the Supremacy Clause invalidates state laws that "interfere with or are contrary to, the laws of congress. . . ." *Gibbons v.*

Ogden, 9 Wheat. 1, 211, 6 L.Ed. 23 (1824). Pre-emption of state law by federal statute or regulation is not favored in the absence of persuasive reasons. *Chicago & North Western Transportation Co. v. Kalo Brick & Tile Co.*, 450 U.S. 311, 317, 101 S.Ct. 1124, 1130, 67 L.Ed.2d 258 (1981); *Florida Lime & Avocado Growers, Inc. v. Paul*, 373 U.S. 132, 142, 83 S.Ct. 1210, 1217, 10 L.Ed.2d 248 (1963). The touchstone of a pre-emption analysis is congressional intent, which may be either express or implied. *Fidelity Federal Savings & Loan Association v. De La Cuesta*, 458 U.S. 141, 151, 102 S.Ct. 3014, 3022, 73 L.Ed.2d 664, 675 (1982); *Jones v. Rath Packing Co.*, 430 U.S. 519, 529, 97 S.Ct. 1305, 1309, 51 L.Ed.2d 604 (1977); *Howard v. Uniroyal, Inc.*, 719 F.2d 1552 at 1555-56 (11th Cir. 1983). In *Florida Lime & Avocado Growers, Inc. v. Paul*, 373 U.S. at 143, 83 S.Ct. at 1218, 10 L.Ed.2d 248, the Supreme Court stated a two-pronged analysis for pre-emption claims: "Does either the nature of the subject matter, ... or any explicit declaration of congressional design to displace state regulation, require [the challenged legislation] to yield to the federal [regulatory scheme]?" We must first examine the federal law for an explicit declaration of Congress's intent to pre-empt state law.

Blood and blood components are biological products subject to the Public Health Service Act, 42 U.S.C.A. § 262 (1982), and are drugs subject to the Federal Food, Drug, and Cosmetic Act, 21 U.S.C.A. § 321(g)(1) (1972). *See Blank v. United States*, 400 F.2d 302, 305-06 (5th Cir. 1968); *United States v. Calise*, 217 F.Supp. 705, 709 (S.D.N.Y. 1962). The Public Health Service Act establishes licensing and product standards and the Federal Food, Drug, and Cosmetic Act provides that unadulterated drugs may not be shipped in interstate commerce. Neither

statute expressly precludes state action[1]. Nor do the applicable regulations explicitly dictate pre-emption[2]. *See* 21 C.F.R. §§ 600.3-680.26 (1983).

[3] Having found no express intent to pre-empt state law, we next examine Congress's implicit intent in enacting the federal scheme. "Where Congress has not stated specifically whether a federal statute has occupied a field in which the states are otherwise free to legislate, different criteria have furnished touchstones for decision." *Pennsylvania v. Nelson*, 350 U.S. 497, 501-02, 76 S.Ct. 477, 479-80, 100 L.Ed. 640 (1956) (footnote omitted). *Accord Howard v. Uniroyal, Inc.*, 719 F.2d 1552 at 1556 (11th Cir. 1983). Three tests are set out in *Pennsylvania v. Nelson* to determine if state law is implicitly pre-empted.

The first test is whether the federal scheme is so pervasive as to make reasonable the inference that Congress left no room for the states to supplement it. *Pennsylvania v. Nelson*, 350 U.S. at

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[1] The attorney for the American Blood Resources Association and the Florida Association of Plasmapheresis Establishment, parties who appeared as amici curiae, argue that section 351 of the Public Health Service Act explicitly expresses Congress's intent to pre-empt state law. Section 351 provides in relevant part:

> (a) No person shall sell, barter or exchange, ... or send, carry or bring for sale, barter or exchange ... any ... blood, blood component or derivative ... unless (1) such ... blood, blood component, or derivative ... has been propagated or manufactured and prepared at an establishment holding an unsuspended and unrevoked license, issued by the Secretary as hereinafter authorized, ... (d) Licenses for the maintenance of establishments ... may be issued only upon a showing that the establishment and the products for which a license is desired meet standards, designed to insure the continued safety, purity, and potency of such products, prescribed in regulations .... All such licenses shall be issued, suspended, and revoked as prescribed by regulations....

42 U.S.C.A. § 262 (1982).

This Court does not find that the statute contains express language indicating pre-emption. *Cf., Armour and Company v. Ball*, 468 F.2d 76 (6th Cir. 1972), *cert. denied*, 411 U.S. 981, 93 S.Ct. 2267, 36 L.Ed.2d 957 (1973) (federal statute in question expressly provided that requirements in addition to, or different than, those made under the statute may not be imposed by any state).

[2] "Federal regulations have no less pre-emptive effect than federal statutes." *Fidelity Federal Savings & Loan Association v. De La Cuesta*, 458 U.S. 141, 151, 102 S.Ct. 3014, 3022, 73 L.Ed.2d 664 (1982) (Supreme Court found preemption where the preamble accompanying the regulations unequivocally expressed intent to pre-empt conflicting state law). *Accord, United States v. Jones*, 707 F.2d 1334, 1336-37 (11th Cir. 1983).

502, 76 S.Ct. at 480, 100 L.Ed. 640. The federal scheme set out in the statutes and implementing regulations at issue here is comprehensive. The three basic requirements of section 351 of the Public Health Service Act ("Act") are that each establishment producing a biological product be licensed, each product be licensed based on standards designed to insure safety, purity, and potency, and that the package and labeling meet specified standards. 42 U.S.C.A. § 262 (1982). Within the federal regulations implementing the Act, 21 C.F.R. §§ 600.3-26 (1983)[3], one part deals specifically with "Source Plasma (Human)," which is defined as the fluid portion of human blood collected by plasmapheresis and intended as source material for further manufacturing use. 21 C.F.R. §§ 640.60-640.76 (1983)[4]. Other portions of the regulations implementing the Act also apply to plasmapheresis[5].

The federal regulations are broad in scope and cover virtually every phase of the plasmapheresis process. The pervasiveness of the regulatory scheme makes it reasonable to infer that

[3] Pursuant to Section 361 of the Act, 42 U.S. C.A. § 264 (1982), and under authority delegated to him, 21 C.F.R. § 5.10, the Commissioner of Food and Drugs is authorized to promulgate regulations. When an administrator promulgates regulations intended to pre-empt state law, the court will not disturb his efforts unless he has exceeded his statutory authority or acted arbitrarily. In examining pre-emption regulations, the court must ask whether the administrator intended to pre-empt state law, and if so, whether that action is within the scope of the administrator's delegated authority. *Fidelity Federal Savings & Loan Association v. De La Cuesta*, 458 U.S. at 151, 102 S.Ct. at 3022, 73 L.Ed.2d 664. In this case, there is no contention that the regulations promulgated pursuant to the Act exceed statutory authority. It does not appear to the Court that the regulations extend beyond the authority granted by Congress.

[4] The regulations prescribe rules as to consent of a prospective donor, medical supervision of the procedure, suitability of donors, method of collection, requirements of the plasmapheresis procedure, immunization of donors, testing for hepatitis, processing of the blood, pooling, inspection, labeling, manufacturing responsibility, records, reporting of fatal donor reactions, modification of source plasma, alternate procedures, and products stored or shipped at unacceptable temperatures.

[5] The subjects included within the remaining regulations are establishment standards and inspection, 21 C.F.R. §§ 600.3-22 (1983); licensing, 21 C.F.R. §§ 601.1-601.33 (1983); good manufacturing practices for blood and blood components, 21 C.F.R. §§ 606.3-606.170 (1983) (with specific sections relating to personnel, facilities, equipment, supplies and reagents, standard operating procedures, finished product and laboratory controls, labeling, records, and reports); establishment registration and product listing, 21 C.F.R. §§ 607.3-607.65 (1983); general biological products standards, 21 C.F.R. §§ 610.65 (1983) (including standards of potency, hepatitis requirements, dating periods, and labeling standards).

Congress left no roon *sic* for local ordinances to supplement it. *See Howard v. Uniroyal, Inc.*, 719 F.2d 1552 at 1559 (11th Cir. 1983). Nevertheless, pre-emption is not to be inferred merely from the comprehensiveness of the federal scheme. *New York State Department of Social Services v. Dublino*, 413 U.S. 405, 415, 93 S.Ct. 2507, 2514 37 L.Ed.2d 688 (1973).

The second test under *Pennsylvania v. Nelson* is whether the federal statute touches a field in which the federal interest is so dominant that the federal system must be assumed to preclude enforcement of state laws on the same subject. *Pennsylvania v. Nelson*, 350 U.S. at 504, 76 S.Ct. at 481, 100 L.Ed. 640. Congress has maintained extensive and comprehensive control over the nation's blood collection since 1946. 38 Fed.Reg. 2966 (1973). The collection of blood is an area of national concern, for "[h]uman blood is a priceless resource." 39 Fed.Reg. 18614 (1974). According to the Commissioner of Food and Drugs:

> The promulgation of standards for these biological drugs is part of an existing effort to increase the quality of blood related health care in this country. Pursuant to the findings of a special Task Force in Blood Banking, the Secretary of Health, Education, and Welfare has established a *comprehensive National Blood Policy*. One of the fundamental methods prescribed by the Secretary to implement the policy is to "employ the full regulatory authorities now vested in the Federal Government ... for the purpose of assuring uniform adherence to the highest attainable standards of practice in blood banking, including plasmapheresis and plasma fractionation."

39 Fed.Reg. 18614 (1974) (emphasis added). *See also* 39 Fed.Reg. 18615 (1974) ("Such regulations are within the broad Congressional mandate to pursue the high remedial public health purpose of both the Federal Food, Drug and Cosmetic Act and the Public Health Service Act.") Furthermore, the Supreme Court has indicated that the Food, Drug, and Cosmetic Act should be given a liberal construction consistent with its overriding purpose to protect the public health. *See United States v. An Article of Drug ... Bacto-Unidisk ...*, 394 U.S. 784, 798, 89 S.Ct. 1410, 1418, 22 L.Ed.2d 726 (1960); *United States v. Dotterweich*, 320 U.S. 277, 280, 64 S.Ct. 134, 136, 88 L.Ed. 48 (1943).

Although the County possesses an interest in the health of

its residents, federal laws may still preclude enforcement of the County scheme. *See Fidelity Federal Savings & Loan Association v. De La Cuesta*, 458 U.S. 141, 151, 102 S.Ct. 3014, 3022, 73 L.Ed.2d 664 (1982) (pre-emption is not inapplicable simply because real property is a matter of special concern to the states). The regulations clearly express a federal interest in establishing a uniform "National Blood Policy." *Cf. Florida Lime & Avocado Growers, Inc. v. Paul*, 373 U.S. 132, 143-44, 83 S.Ct. 1210, 1218, 10 L.Ed.2d 248 (1963) (the maturity of avocados is an inherently unlikely candidate for exclusive federal regulation). Therefore, we conclude that the federal interest in plasmapheresis is dominant over any local interest.

The third test in *Pennsylvania v. Nelson* is whether the enforcement of state law presents a serious danger of conflict with the administration of the federal program. 350 U.S. at 505, 76 S.Ct. at 482, 100 L.Ed. 640. The Commissioner of Food and Drugs described the purpose of the federal scheme as follows:

> To insure there is a continued healthy donor population to serve as a source of plasma to be used in the manufacture, by the fractionation technique, of safe, pure, and potent blood products, the Commissioner is including in these proposed additional standards for Source Plasma (Human) specific provisions designed to protect the health and well-being of the donor.

37 Fed.Reg. 17420 (1972). Thus, the regulations were designed to protect the plasma donors, to insure that the product is safe, and to insure the continued existence of a healthy donor population. *See also* 39 Fed.Reg. 26162 (1974); 39 Fed.Reg. 18615 (1974); 41 Fed.Reg. 10762-63 (1976). The regulations were also enacted to establish uniform standards for blood banking. 39 Fed.Reg. 26161 (1974). The goal of uniformity runs throughout the regulations. *See, e.g.*, 48 Fed.Reg. 26313 (1983) (one reason for regulations establishing FDA inspection at least once every two years is to provide uniformity in the frequency of inspection).

The purpose of the County scheme is similar to that of the federal scheme. Section 15 of Ordinance 80-12 incorporates by reference the federal regulations appearing at 21 C.F.R. Part 640, Subpart G, Section 640.60 *et seq*. As noted earlier, these are the provisions of the federal regulatory scheme relating solely to

"Source Plasma (Human)." The other provisions of the County Ordinances, however, impose additional requirements on plasmapheresis centers.[6]

These additional County requirements cover areas that are clearly encompassed by the federal regulations. Unlike *Smith v. Pingree*, 651 F.2d 1021, 1025 (5th Cir. 1981) (Unit B), in which the court found that the federal requirements did not regulate every aspect of the area and so the state had the implied reservation to fill out the scheme, the federal scheme here regulates every aspect of plasmapheresis. The County scheme imposes burdensome and expensive requirements in addition to the requirements of the comprehensive federal scheme. If the County scheme remains in effect, the national blood policy of promoting uniformity and guaranteeing a continued supply of healthy donors will be adversely affected. *See Campbell v. Hussey*, 368 U.S. 297, 301, 82 S.Ct. 327, 329, 7 L.Ed.2d 299 (1961) (pre-emption found where act refers to need for uniform official standards); *Howard v. Uniroyal*, 719 F.2d 1552 at 1560 (11th Cir. 1983) (pre-emption found where one of Congress's objectives was to insure that there would be a uniform, consistent federal approach).

Thus, Automated has satisfied the three tests set out in *Pennsylvania v. Nelson*. This Court holds that Hillsborough County Ordinances 80-11 and 80-12 and the implementing rules and regulations are pre-empted by the federal scheme. The Court need not reach any other issues raised on appeal. Accordingly, the judgment of the district court finding Section 7 of Ordinance 80-12 and § 4 of the rules and regulations invalid is AFFIRMED, the judgment finding the remaining sections of the County Ordinances and implementing rules and regulations valid is REVERSED.

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[6] The County scheme adds the following requirements: 1) A person may donate plasma only after obtaining a donor registration card, at a cost of $2.00, valid for six months at a single designated plasma center; 2) a donor registration card is issued only after the donor receives a complete physical exam and a hepatitis test and presents a sworn statement that within the preceding year, he or she has not been treated for chronic or acute alcoholism; 3) the plasma center must keep and forward daily to the Department records of the donors and procedures performed; 4) each donor must undergo a breath analysis prior to donation; 5) the Department shall inspect the plasma center at least once a year, and 6) the plasma center must pay the Department $1.00 for each plasmapheresis procedure performed.

United States Court of Appeals
FOR THE ELEVENTH CIRCUIT

NO. 83-3014

D.C. Docket No. 81-1161[sic]-WC

AUTOMATED MEDICAL LABORATORIES, INC.,
Plaintiff-Appellant,

versus

HILLSBOROUGH COUNTY, FLORIDA, and
HILLSBOROUGH COUNTY HEALTH DEPARTMENT,
Defendants-Appellees.

Appeal from the United States District Court for the
Middle District of Florida

Before FAY and HENDERSON, Circuit Judges, and TUTTLE, Senior Circuit Judge.

J U D G M E N T

This cause came on to be heard on the transcript of the record from the United States District Court for the Middle District of Florida, and was argued by counsel;

ON CONSIDERATION WHEREOF, it is now here ordered and holding adjudged by this Court that the judgment of the District Court finding Section 7 of Ordinance 80-12 and § 4 of the rules and regulations invalid is AFFIRMED; the judgment finding the remaining sections of County Ordinances 80-11 and 80-12 and implementing rules and regulations valid is REVERSED;

It is further ordered that defendants-appellees pay to plaintiff-appellant, the costs on appeal to be taxed by the Clerk of this Court.

ISSUED AS MANDATE: MAR 8- 1984

Entered: January 16, 1984
For the Court: Spencer D. Mercer, Clerk
BY: _____
Deputy Clerk